DPTE® TRANSFER SYSTEM
Autoclavable containers

SPECIFICATION

PRODUCT SPECIFICATION
The DPTE® transfer system is recognized as being the safest method for introducing and removing sterile and/or toxic equipment without breaking containment. The autoclavable DPTE® containers conform to the requirements for sterilization using an autoclave and are equipped with the necessary accessories for ease of use.

APPLICATION
The autoclavable DPTE® containers is mainly used for introducing equipment (pump body, stoppers, capsules…) into an isolator after sterilization using an autoclave. It also allows the removal of objects (the empty container will first have been sterilized using an autoclave).

KEY FEATURES
- 316L stainless steel DPTE® Beta flange and door,
- 316L stainless steel body,
- Hydrophobic filter.

QUALITY STATEMENT
Confidence in the Getinge group is the most important quality criteria. This must be the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge must conform to the agreed terms and expectations to ensure recommendations for further business. The achievement of these quality goals is the basis for continued competitive and successful enterprise.

STANDARDS & CODES
The Autoclavable DPTE® containers complies with all appropriate standards, codes and directives relevant to the region of installation. The equipment is manufactured according to industry requirements and standards. A sample declaration stating the relevant standards, codes and machine directives with which the equipment complies is available on request.

- Denotes optional feature - Check box as required.
- Commercial specifications only.
- Pictures and drawings non contractual.
DESCRIPTION

PRODUCT DESCRIPTION
The autoclavable DPTE® containers is composed of 6 parts:
- Beta flange
- Beta door
- J3L E lip seal
- Rollers
- Body
- Hydrophobic filter

PRINCIPLE OF OPERATION

A reminder of the DPTE® operating principle
- 2 assemblies, Alpha and Beta – 2 seals meeting at a point,
- 4 elements mutually shielding each others faces, locked together by the rotation of the Beta part.

BASIC DESIGN FEATURES
Design features and material definition conform to the specification listed below, unless specifically mentioned as optional.

Beta flange
The beta flange is constructed from solid, high quality, stainless steel (type 316L or European equivalent).
Surfaces are polished to facilitate cleaning (N7=Ra 1,6 µm in accordance with ISO 1302 norm).

Beta door
The Beta door is constructed from solid, high quality, stainless steel (type 316L or European equivalent).
Surfaces are polished to facilitate cleaning (N7=Ra 1,6 µm in accordance with ISO 1302 norm).

J3L E lip seal
A J3L E lip seal made of silicone is mounted onto the Beta flange.
- It ensures the tightness between Beta door and beta flange,
- It ensures the tightness between Alpha and Beta doors when the container is opened.

Rollers
The rollers are made of bronze, it makes connection/disconnection of the Autoclave containers easier with DPTE® alpha (rollers only for 190Ø - 270Ø - 350Ø).

Body
The body is constructed from solid, high quality, stainless steel (type 316L or European equivalent).
Surfaces are polished to facilitate cleaning (External=Ra 1,6 µm /internal Ra 0,8 µm in accordance with ISO 1302 norm).

Hydrophobic filter
It is fitted onto the 1" 1/2 clamp connector and allows the penetration of steam inside the container during the autoclave phase. The larger the surface to be filtered, the better the penetration of steam into the container. Its efficiency is of 0.22 µm.
ORDERING

Description
Use the description below, with the dimension table to select the appropriate model.

Example Model: CT AUT 190/400

<table>
<thead>
<tr>
<th>Name</th>
<th>Model Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT AUT MODELS</td>
<td></td>
</tr>
<tr>
<td>CT AUT 105/400</td>
<td></td>
</tr>
<tr>
<td>CT AUT 190/400</td>
<td></td>
</tr>
<tr>
<td>CT AUT 270/400</td>
<td></td>
</tr>
<tr>
<td>CT AUT 350/500</td>
<td></td>
</tr>
</tbody>
</table>

Accessory
Each autoclavable container is delivered:
- Door key,
- Seal protection cover.

Door key
To open or close the container door (available for all diameters).
The key is made of PVC (polyvinyl chloride).

Seal protection cover
This seal protection cover the gasket during autoclaving (available for all diameters).
The seal protection cover is made of aluminium.

DIMENSIONS
(Diagrams and tables)

<table>
<thead>
<tr>
<th>Model Number</th>
<th>105Ø</th>
<th>190Ø</th>
<th>270Ø</th>
<th>350Ø</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal Ø</td>
<td>95</td>
<td>170</td>
<td>250</td>
<td>332</td>
</tr>
<tr>
<td>Useful Ø (mm)</td>
<td>100</td>
<td>192</td>
<td>272</td>
<td>354</td>
</tr>
<tr>
<td>Int. Useful Ø (mm)</td>
<td>144*</td>
<td>424</td>
<td>509</td>
<td>581</td>
</tr>
<tr>
<td>Overall Ø (mm)</td>
<td>400</td>
<td>400</td>
<td>400</td>
<td>500</td>
</tr>
<tr>
<td>Overall length (mm)</td>
<td>349</td>
<td>546</td>
<td>549</td>
<td>649</td>
</tr>
<tr>
<td>Useful volume (L)</td>
<td>3</td>
<td>11.5</td>
<td>23</td>
<td>48.9</td>
</tr>
<tr>
<td>Weight when empty (kg)</td>
<td>4.5</td>
<td>8</td>
<td>10</td>
<td>15.5</td>
</tr>
<tr>
<td>Maximum acceptable load (kg)</td>
<td>5</td>
<td>15</td>
<td>25</td>
<td>40</td>
</tr>
</tbody>
</table>

*No handle on the 105

OPTION LIST
- Stainless steel seal protection cover (type 316L or European equivalent).
- Other Useful length to consult us.
- Additionnal tri clamp to consult us.

SERVICES
Check
Standard:
Autoclavable DPTE® containers are inspected before shipment.
This operation is carried out by our Inspection Quality Department.
Inspections sheets are signed by the Inspection Quality Department and the Quality Internal Validation Department.
Documentation

Standard:
- English language
- French language

For each unit, a certificate is delivered including:
- Material certificate
- Checks
- Statement of conformity

Option list:
- Other language: ............................
- Operating file includes:
  - Assembly drawing
  - Operation manual and recommendations
  - Factory acceptance procedure
  - Inspection note
  - Material certificate
  - Statement of conformity
- Microbiological qualification report
- Particulate contamination qualification report

PACKING AND OPTIONS

Packaging identification
- Item,
- Quantity,
- Assembly.

Packing method
- The autoclavable DPTE® containers is packed into card board box

Storage conditions
- Normal storage temperature (16°C and 24°C).

INSTALLATIONS

Limits of use / specification

Service conditions
- During sterilization:
  - Autoclave temperature: < 125°C,
  - Autoclave pressure: 30 mbars (relative pressure).

Operating:
- Operating temperature: between +16° C and +24° C,
- Pressure: between -150 Pa and +150 Pa (relative pressure).

Limits of resistance:
- Range of temperature : 0° C / + 150° C,
- Test pressure : – 5 000 Pa / + 5 000 Pa.

Specifications for leak tightness:
- Acceptable leak after manufacturing from Getinge-La Calhène are half acceptable leak in operation,

Maximum volumetric leakage rate in cm³ . s⁻¹ in operation at 500 Pa

<table>
<thead>
<tr>
<th></th>
<th>105Ø</th>
<th>190Ø</th>
<th>270Ø</th>
<th>350Ø</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.10⁻³</td>
<td>2.10⁻³</td>
<td>3.10⁻³</td>
<td>4.10⁻³</td>
<td></td>
</tr>
</tbody>
</table>

Example: The acceptable leak after manufacturing from Getinge-La Calhène is 2.10⁻³ cm³ . s⁻¹ at 500 Pa for a 350 autoclavable DPTE® containers.

Cleaning
- Soft lint free cloth,
- Cleaning agent (check for material compatibility).

Compatible types of DPTE® Alpha
- DPTE®-S with safety interlocks (105Ø to 350Ø),
- DPTE®-ISO without safety interlocks (105Ø to 350Ø).

ACCESSORIES
- Basket
- Elevating and mobile transportation trolley

Basket
The basket allows the storage and the introduction of the autoclavable container load. It ensures that steam circulates freely in the container and that there are no hidden or non-exposed surfaces. The assembly are manufactured of stainless steel (type 316L).

<table>
<thead>
<tr>
<th></th>
<th>190Ø</th>
<th>270Ø</th>
<th>350Ø</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useful length (mm)</td>
<td>370.5</td>
<td>373</td>
<td>470</td>
</tr>
<tr>
<td>Useful volume (L)</td>
<td>7.7</td>
<td>17</td>
<td>39</td>
</tr>
<tr>
<td>Weight of the basket when empty (kg)</td>
<td>1.3</td>
<td>2.2</td>
<td>3.7</td>
</tr>
<tr>
<td>Weight of the basket guide when empty (kg)</td>
<td>0.2</td>
<td>0.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Elevating and mobile transportation trolley
Elevating and mobile transportation trolley adjustable in height and depth direction facilitate and make safe the transportation of the container (from the autoclave to the docking point) and the container connection onto the DPTE® alpha.

The frame is made of stainless steel 304L, fitted on four casters lockable in polyamide, on which an hydraulic manual pump system with four cylinders allows a height adjustment of 150 mm. The container height of connection (the axis of the DPTE® alpha) must be between 1200 and 1350 mm.
On the plate, a PVC support in two parts ensures the good position of the container. The higher part (arch) fitted on the hinge comes to lock the container with the two eyelets bolts. Elevating and mobile transportation trolley 190Ø - 270Ø 350Ø only.

It comprises five main parts:

- Arch
- Translation support for container
- Translation guide
- Frame
- Jack actuator

Replacement of the J3L E lip seal
The J3L E lip seal must be replaced every 2 years. However it is recommended to carry out a periodic visual check of the lip seal conditions and to proceed with a replacement if necessary (in case of cuts or removal of material).

<table>
<thead>
<tr>
<th>Elevating and mobile transportation trolley</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYPE</td>
</tr>
<tr>
<td>Part number</td>
</tr>
<tr>
<td>Index finger with locking device</td>
</tr>
<tr>
<td>Locking caster</td>
</tr>
<tr>
<td>Roller</td>
</tr>
<tr>
<td>Roller shaft</td>
</tr>
</tbody>
</table>

RELATED & OTHER APPROPRIATE PRODUCTS
DESCRIPTION
The TLT (Transfer Leak Tester) is designed to check the integrity of the DPTE® beta.

It allows to test:

- DPTE® beta empty (DPTE® beta upside down onto the test plate) or filled ones, in air or sterile atmosphere (test plate fixed onto the DPTE® beta).
- DPTE® alpha parts.

List of spare parts

<table>
<thead>
<tr>
<th>Autoclavable DPTE® containers models</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYPE</td>
</tr>
<tr>
<td>Part number</td>
</tr>
<tr>
<td>Description</td>
</tr>
<tr>
<td>J3L E lip seal</td>
</tr>
<tr>
<td>Hydrophobic filter</td>
</tr>
<tr>
<td>Seal protection cover</td>
</tr>
<tr>
<td>Collar 1” ½ clamp</td>
</tr>
<tr>
<td>Plug 1” ½ clamp</td>
</tr>
<tr>
<td>Seal 1” ½ clamp</td>
</tr>
<tr>
<td>Door key</td>
</tr>
<tr>
<td>Device for replacing the J3L lip seal.</td>
</tr>
</tbody>
</table>

Frequency of replacement

<table>
<thead>
<tr>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3L E lip seal</td>
<td>Once every 2 years</td>
</tr>
</tbody>
</table>

GLOSSARY

DPTE®-S: safety double door transfer system with safety interlocks (alpha flange + alpha door + J3L I).
DPTE®-ISO: safety double door transfer system without safety interlocks (alpha flange + alpha door + J3L I).
DPTE® Beta: beta flange + beta door + J3L E.
J3L I: internal 3 effect lip seal.
J3L E: external 3 effect lip seal.
TLT: Transfer Leak Tester
Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.